March 29, 1999

NEW FDA REQUEST

For Information Regarding Status of Year 2000-*Compliant* Products

Dear Biomedical Equipment Manufacturer:

This letter is to request that you submit a complete list of your vulnerable product models that are Year 2000 compliant to the FDA-operated Federal Y2K Biomedical Equipment Clearinghouse.

In a previous letter, dated January 13, 1999, we advised you of FDA's plans to expand the product information maintained on the FDA-operated Federal Y2K Biomedical Equipment Clearinghouse, and asked for your continuing cooperation in this effort. Thus far, we have asked that you furnish information regarding Y2K non-compliant products or a statement that all of your products are Y2K compliant. However, many biomedical equipment users have told us that this single statement regarding compliance does not meet their need to have affirmatively identified specific compliant equipment. They have expressed the need for specific information on all Y2K-vulnerable compliant products and urged the establishment of a single, comprehensive source for this information.

This new database of Y2K compliant products is intended to provide information on products that biomedical equipment users might consider to be vulnerable to date-related problems because these products utilize software, a computer or microprocessor control. Accurate Y2K status information on these products is critical to these users as they evaluate their product inventory and plan any needed remedial actions. Products that do not use software, a computer or microprocessor control and would not be anticipated by users to be affected by the Year 2000 date change or other date-related problems need not be included.

This special Year 2000 data gathering request is being made pursuant to the Year 2000 Information and Readiness Disclosure Act. We will use the product information you provide to help make the Y2K Clearinghouse a comprehensive source of product status information for healthcare facilities. Please note that providing us with only a URL for a manufacturer-operated web site will not fulfill the intent of this request, because biomedical equipment users desire to be able to search this database using search criteria other than manufacturer name and providing only a URL does not permit this.

To assist you in this important effort, we have included detailed instructions with this letter that describe the type of information and level of detail we are seeking. The Y2K Clearinghouse, copies of forms, and information regarding submissions can be found on the FDA web site at the URL http://www.fda.gov by selecting "Year 2000".

Your prompt attention to this request will help assure that the Y2K Clearinghouse is a useful and comprehensive resource for biomedical equipment users who require this information for the safe delivery of patient care as we move into the year 2000. I strongly urge you to work with us on this effort and to respond with the requested information by April 30, 1999.

Sincerely yours,

Elizabeth D. Jacobson, Ph.D.
Acting Director,
Center for Devices and Radiological Health

Enclosures: Instruction Sheet
Options for Reporting Biomedical Equipment That Is Y2K Compliant
Electronic File (E-File) Reporting Format Instructions
Forms for Information Reporting
List of Product Classification Names